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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,728	01/22/2001	Habib Zaghouani	ALTA.143C1	6688

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EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/623,728	Zaghouani
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Dec 31, 2002* .

2a) [X] This action is **FINAL.** 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *8-20* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-7 and 21-28* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___
4) [ ] Interview Summary (PTO-413) Paper No(s). ___
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

Part III DETAILED ACTION

1. Claims 1-20 and newly added claims 21-28 are pending.

2. Claims 8-20 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, for reasons set forth in Paper No. 13.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 and 21-28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons set forth in Paper No. 13.

Applicant's arguments filed 12-31-02 have been fully considered but are not found persuasive.

Applicant argues they have support for the phrase is derived from a protein responsible for an autoimmune disease by the disclosure of agonists that may be derived from autoantigenic polypeptides as disclosed on page 8 lines 19-22.

However, the Examiner does not disagree that they have support for agonists derived from autoantigenic polypeptides, what is at issue is that in many if not most autoimmune diseases it is not known which autoantigen is responsible for the disease, it is well recognized which autoantigens the body makes an inappropriate immune response to once the disease has already started in a human, but what the original autoantigen is not known for most autoimmune diseases and therefore Applicant has no written support for derived from a polypeptide responsible for an autoimmune disease. The Examiner has included page 1061 from the Merck Manual of Diagnosis and Therapy for Applicant's consideration. Applicant is guided to In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981) recognized that "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of

circumstances is not sufficient.' In other since it is not clear what causes autoimmune disorders and Applicant does not have ipsis verbis support for the claim recitation, it is new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 1-7 and 21-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (26) in view of Liu et al., (59) and Karpus et al.,(51), for reasons of record set forth in Paper No. 13.

Applicant's arguments filed 12-31-02 have been fully considered but are not found persuasive.

Applicant argues "However, the mechanism suggested in Bona probably would not work to lessen or stop an autoimmune response because MHC molecules and pathogenic peptides are constantly being synthesized in unlimited amounts inside the APC's and the introduced peptide would be outcompeted over time. At best, a transitory competition might occur and whether this would actually result in lessening or prevention of an autoimmune response even for a short period is open to question. Bona is merely speculating and provides no examples, data or results to support the hypothesis. Thus Applicant believes that the combination of Bona in view of Liu and/or Karpus is not enabling prior art for the purpose asserted by the Examiner."

However, as recognized by the MPEP in section 2145, Attorney argument is not evidence. Applicant's representative can not assert the fusion protein made obvious by the prior art references are not enabled without objective evidence. Furthermore, Applicant's claims are drawn to products with no recited functional limitation. Therefore the only burden on the Examiner as far as expectation of success is concerned would be to make the products what properties they have is immaterial since those properties are not recited.

Applicant also argues there was not motivation to make the claimed products. However, the peptides used for inducing tolerance were known, the immunoglobulin carrier construct was already known, and it was already known that linear peptide therapy had significant drawbacks curable by using an immunoglobulin construct taught by Bona. Applicant is guided to, In re Rosselet, 146 USPQ 183,(CCPA 1965), which recognized The test for obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
March 23, 2003